# UNITED STATES DISTRICT COURT NORTHERN DISTRICT OF GEORGIA ATLANTA DIVISION

STIEFEL LABORATORIES, INC.,	)	
	)	
Plaintiff, v.	)	CIVIL ACTION NO.
	)	1:08-CV-3773
	)	
	)	JURY TRIAL DEMANDED
BROOKSTONE	)	
PHARMACEUTICALS, L.L.C.	)	
	)	
	)	
Defendant.	)	
	)	

#### **ANSWER**

Brookstone Pharmaceuticals, LLC files this Answer to Stiefel Laboratories, Inc.'s Original Complaint, denying its allegations of false advertising and unfair competition under Section 43(a) of the Lanham Act and common law unfair competition. Stiefel's Complaint comprises nothing more than an abusive litigation intended to: unfairly and illicitly protect the profits it has realized on the sale of its acne treatment BREVOXYL Gel; intimidate and harass Brookstone and to prohibit its legal and desirable participation in the

marketplace for acne treatment products; and ward off legitimate competitors who provide acne sufferers with effective, legal, and lower cost alternatives to Stiefel's products. By way of specific defense, Brookstone states as follows:

#### AFFIRMATIVE DEFENSES

# First Affirmative Defense

Stiefel has failed to state a claim upon which relief can be granted. By Stiefel's own admission: (1) Brookstone did not violate Stiefel's patent on BREVOXYL Gel in developing BPO Gel, and (2) Brookstone's BPO Gel contains benzoyl peroxide - the same active ingredient as Stiefel's BREOVOXYL Gel - also suspended in a topical gel. There is no dispute that benzoyl peroxide is a commonly available, generic ingredient. Originally, Stiefel alleged that the essential difference between its product and Brookstone's product was the presence of dimethyl isosorbide, which is delivery agent for benzoyl peroxide into the skin. After Brookstone pointed out that

Stiefle's claim was false because BPO Gel does, in fact, contain dimethyl isosorbide, Stiefel amended Complaint by deleting its allegations regarding dimethyl isosorbide and adding claims that BPO Gel contains benzyl alcohol and aloe, and that the benzyl alcohol in particular raises the danger of BPO Gel being "both irritating and comedogenic." What Stiefel ignores is that it routinely utilizes benzyl alcohol in its own acne treatments, including those incorporating benzoyl Stiefel has failed to identify how peroxide. introduction of aloe makes any material difference between BPO Gel and BREVOXYL Gel. Stiefel has alleged no facts showing Brookstone's BPO Gel is not a valid competitive product, offering the marketplace a viable, legal alternative to its own BREVOXYL Gel. Developing a cheaper alternative product is the essence of free market competition. Stiefel's Complaint offends the very free market principals from which it profits. Stiefel's claims are meritless and should be dismissed, with prejudice.

# Second Affirmative Defense

Stiefel is barred from legal relief because it is in pari delicto with the Brookstone and it is barred from receiving equitable relief by the doctrine of unclean hands. Specifically, to the extent BPO Gel fails to help treat acne, so would BREVOXYL Gel, as both utilize the same active ingredients and equivalent inactive ingredients. Further, Stiefel is abusing litigative procedure to prohibit legitimate, lawful competition. As such Stiefel is acting in manifest bad faith and from improper motive.

#### Third Affirmative Defense

Brookstone comported at all times with its legal obligations and duties and has committed no action or offense that could comprise the basis for Stiefel's Complaint.

# Fourth Affirmative Defense

Stiefel is estopped from asserting and has waived the claims asserted. Stiefel has allowed other competitors

utilizing products substantially similar to Brookstone's BPO Gel to compete freely with its BREVOXYL Gel.

#### Fifth Affirmative Defense

No act or omission on the part of Brookstone either caused or contributed to whatever injury or harm Steifel alleges it sustained.

# Sixth Affirmative Defense

The Complaint is barred because Stiefel has failed to allege any injury for which damages can be awarded.

# Seventh Affirmative Defense

The Complaint is barred because any injury allegedly suffered by Stiefel is as a result of its own negligence and misconduct and cannot be ascribed to the action or inaction of Brookstone.

# Eighth Affirmative Defense

To the extent Stiefel may claim or be found to be entitled to equitable relief, Stiefel's claims are barred by the doctrine of laches.

# Ninth Affirmative Defense

Stiefel's claims are barred because of lack of damages. Additionally, to the extent any damages may be established, they are too remote and speculative to permit recovery.

#### Tenth Affirmative Defense

Stiefel failed to adequately mitigate its alleged damages.

#### Eleventh Affirmative Defense

Stiefel has inflicted harm upon Brookstone's interests due to its misconduct and negligent acts, for which Brookstone claims the rights of setoff and recoupment.

# Twelfth Affirmative Defense

Stiefel's claims are barred in whole or in part because Stiefel filed the Complaint for the improper purpose of intimidating and harassing Brookstone. Stiefel is claiming rights and harm which cannot be substantiated.

# Thirteenth Affirmative Defense

Stiefel has failed to plead with particularity those elements, which should be so pled, including, without limitation, pre-suit notice mandated under O.C.G.A. § 10-1-399.

#### ADMISSIONS AND DENIALS

The above Affirmative Defenses are repeated and incorporated herein by reference. Responding to each of the numbered Paragraphs of Stiefel's Complaint, Brookstone shows the Court:

# <u>Parties</u>

1.

Brookstone is without sufficient knowledge or information to either admit or deny the allegation made, and the same is, accordingly, denied.

2.

Brookstone objects to paragraph 2 of the Complaint, on the grounds that it is comprised of lengthy compound allegations, implications, insinuations, and innuendo, in

violation of Fed. R. Civ. Proc. 8 (a), (d). Without waiving and subject to such objection, Brookstone admits that it distributes BPO 4% Gel and BPO 8% Gel to the marketplace, including in this District. All other allegations not specifically admitted are hereby denied.

3.

Brookstone admits that this Court has subject matter jurisdiction. All other allegations not specifically admitted are hereby denied.

4.

Brookstone objects to paragraph 4 of the Complaint, on the grounds that it is comprised of lengthy compound allegations, implications, insinuations, and innuendo, in violation of Fed. R. Civ. Proc. 8 (a), (d). Without waiving and subject to such objection, Brookstone admits: (1) this Court has in personam jurisdiction; (2) that it promotes and sells BPO Gel within the Northern District of Georgia and elsewhere; and (3) that its BPO Gel product has been and presently is being purchased by

consumers in the marketplace. All other allegations not specifically admitted are hereby denied.

5.

Brookstone admits the allegation made in paragraph 5 of the Complaint.

# Background

6.

Brookstone objects to paragraph 6 of the Complaint, on the grounds that it is comprised of lengthy compound allegations, implications, insinuations, and innuendo, in violation of Fed. R. Civ. Proc. 8 (a), (d). Without waiving and subject to such objection, Brookstone admits that there is an active market for various acne treatment products. All other allegations not specifically admitted are hereby denied.

7.

Brookstone is without sufficient knowledge or information to either admit or deny the allegations made, and the same are, accordingly, denied.

Brookstone objects to paragraph 8 of the Complaint, on the grounds that it is comprised of lengthy compound allegations, implications, insinuations, and innuendo, in violation of Fed. R. Civ. Proc. 8 (a), (d). Without waiving and subject to such objection, Brookstone admits that benzoyl peroxide has long been recognized as a treatment for acne. All other allegations not specifically admitted are hereby denied.

9.

Brookstone objects to paragraph 8 of the Complaint, on the grounds that it is comprised of lengthy compound allegations, implications, insinuations, and innuendo, in violation of Fed. R. Civ. Proc. 8 (a), (d). Without waiving and subject to such objection, Brookstone is without sufficient knowledge or information to either admit or deny the allegations made, and the same are, accordingly, denied.

Brookstone objects to paragraph 8 of the Complaint, on the grounds that it is comprised of lengthy compound allegations, implications, insinuations, and innuendo, in violation of Fed. R. Civ. Proc. 8 (a), (d). Without waiving and subject to such objection, Brookstone is without sufficient knowledge or information to either admit or deny the allegations made, and the same are, accordingly, denied.

11.

Brookstone admits that it specializes in "reducing pharmaceutical costs" by developing "niche generic pharmaceuticals, overlooked ANDA's [Abbreviated New Drug Applications for Generic Drugs] and difficult to manufacture products." Brookstone is unsure of the source of Stiefel's alleged quote and the same, including all other allegations not specifically admitted, are hereby denied.

Brookstone admits it introduced its BPO Gel in 2008 to serve the needs of acne sufferers. All other allegations not specifically admitted are hereby denied.

13.

Brookstone objects to paragraph 13 of the Complaint, on the grounds that it is comprised of lengthy compound allegations, implications, insinuations, and innuendo, in violation of Fed. R. Civ. Proc. 8 (a), (d). Without waiving and subject to such objection, Brookstone admits that its BPO Gel is manufactured under its own formula, utilizing, in whole or in part, the same, generally available and generic active ingredients as Stiefel's BREVOXYL Gel. Brookstone has marketed BPO Gel as a viable, competing alternative to other treatments in the marketplace. All other allegations not specifically admitted are hereby denied.

14.

Brookstone objects to paragraph 14 of the Complaint, on the grounds that it is comprised of lengthy compound

allegations, implications, insinuations, and innuendo, in violation of Fed. R. Civ. Proc. 8 (a), (d). Without waiving and subject to such objection, Brookstone admits that it has marketed its BPO Gel as a viable alternative to more expensive, competing products in the marketplace. All other allegations not specifically admitted are hereby denied.

15.

Brookstone objects to paragraph 15 of the Complaint, on the grounds that it is comprised of lengthy compound allegations, implications, insinuations, and innuendo, in violation of Fed. R. Civ. Proc. 8 (a), (d). Without waiving and subject to such objection, Brookstone's press releases speaks for themselves and do not require a response. Certainly, Brookstone's mission statement, which comprises a wholly legal activity within the marketplace, furnishes no evidence of wrongdoing. Further, Brookstone is without sufficient knowledge or information to either admit or deny allegations regarding what other persons in the marketplace might or might not

say about Brookstone's products, and the same is thus denied. All other allegations not specifically admitted are hereby denied.

16.

Brookstone admits that its BPO Gel competes with other products for the treatment of acne, which would include, but is not limited to, Stiefel's BREVOXYL Gel. All other allegations not specifically admitted are hereby denied.

17.

Brookstone objects to paragraph 17 of the Complaint, on the grounds that it is comprised of lengthy compound allegations, implications, insinuations, and innuendo, in violation of Fed. R. Civ. Proc. 8 (a), (d). Without waiving and subject to such objection, Brookstone is without sufficient knowledge or information to either admit or deny what other persons in the marketplace may state regarding its BPO Gel, except to the extent previously and specifically admitted, or how they market or link such product compared to Brookstone's

competitors. All other allegations not specifically admitted are hereby denied.

18.

Brookstone is without knowledge or information sufficient to either admit or deny the allegations made and the same are, accordingly, denied.

19.

Brookstone objects to paragraph 19 of the Complaint, on the grounds that it is comprised of lengthy compound allegations, implications, insinuations, and innuendo, in violation of Fed. R. Civ. Proc. 8 (a), (d). Without waiving and subject to such objection, paragraph 19, in recounting the statutory and regulatory requirements and purposes pertinent to the manufacture and sale of generic drugs, is calling for a legal conclusion, to which no response is required, although to the extent any wrongful conduct or liability is implied, the same is denied.

20.

Brookstone objects to paragraph 20 of the Complaint, on the grounds that it is comprised of lengthy compound

allegations, implications, insinuations, and innuendo, in violation of Fed. R. Civ. Proc. 8 (a), (d). Without waiving and subject to such objection, paragraph 20, in recounting the statutory and regulatory requirements and purposes pertinent to the manufacture and sale of generic drugs, is calling for a legal conclusion, to which no response is required, although to the extent any wrongful conduct or liability is implied, the same is denied.

21.

Paragraph 21, in recounting the statutory and regulatory requirements and purposes pertinent to the manufacture and sale of generic drugs, is calling for a legal conclusion, to which no response is required, although to the extent any wrongful conduct or liability is implied, the same is denied.

22.

Brookstone objects to paragraph 22 of the Complaint, on the grounds that it is comprised of lengthy compound allegations, implications, insinuations, and innuendo, in violation of Fed. R. Civ. Proc. 8 (a), (d). Without

waiving and subject to such objection, Brookstone admits that: (1) its BPO Gel treats acne as effectively as Stiefel's BREVOXYL Gel; (2) it did not copy or otherwise replicate Stiefel's formula for BREVOXYL Gel; and (3) that it and Stiefel are not the same company and thus perforce, BPO Gel and BREVOXYL Gel must be produced by different manufacturers. All other allegations not specifically admitted are hereby denied.

23.

Brookstone admits that its BPO Gel competes with other products that treat acne, including Stiefel's BREVOXYL Gel, that it has marketed its BPO Gel as a viable, lower cost alternative to these other treatments, and that the marketplace is purchasing its BPO Gel. All other allegations not specifically admitted are denied.

24.

Brookstone denies the allegations made in paragraph 24 of the Complaint.

# COUNT 1: <u>Violation of Lanham Act Section 43(a)</u> (False Advertising)

25.

Brookstone incorporates by reference each of the foregoing paragraphs as if fully restated herein.

26.

Brookstone admits that its sells, advertizes, markets, and distributes its products, including its BPO Gel to intermediary and final purchasers. All other allegations not specifically admitted are hereby denied.

27.

Brookstone denies the allegations made in paragraph 27 of the Complaint.

28.

Brookstone denies the allegations made in paragraph 28 of the Complaint.

29.

Brookstone denies the allegations made in paragraph 29 of the Complaint.

Brookstone denies the allegations made in paragraph 30 of the Complaint.

31.

Brookstone denies the allegations made in paragraph 31 of the Complaint.

# COUNT 2: <u>Violation of Lanham Act Section 43(a)</u> (Unfair Competition)

32.

Brookstone incorporates by reference each of the foregoing paragraphs as if fully restated herein.

33.

Brookstone is without knowledge or information sufficient to either admit or deny the allegations made and the same are, accordingly, denied.

34.

Brookstone denies the allegations made in paragraph 34 of the Complaint.

Brookstone denies the allegations made in paragraph 35 of the Complaint.

36.

Brookstone denies the allegations made in paragraph 31 of the Complaint.

37.

Brookstone denies the allegations made in paragraph 37 of the Complaint.

38.

Brookstone denies the allegations made in paragraph 38 of the Complaint.

39.

Brookstone denies the allegations made in paragraph 39 of the Complaint.

# COUNT 3: <u>Violation of the Georgia Uniform Deceptive</u> Practices Act

40.

Brookstone incorporates by reference each of the foregoing paragraphs as if fully restated herein.

41.

Paragraph 41 calls for a legal conclusion and no response, therefore, is required. To the extent any wrongdoing or liability is implied, the same is denied.

42.

Paragraph 42 calls for a legal conclusion and no response, therefore, is required. To the extent any wrongdoing or liability is implied, the same is denied.

43.

Brookstone denies the allegations made in paragraph 43 of the Complaint.

44.

Brookstone denies the allegations made in paragraph 44 of the Complaint.

Brookstone denies the allegations made in paragraph 45 of the Complaint.

46.

Brookstone denies the allegations made in paragraph 46 of the Complaint.

# COUNT 4: Common Law Unfair Competition

47.

Brookstone incorporates by reference each of the foregoing paragraphs as if fully restated herein.

48.

Brookstone denies the allegations made in paragraph 48 of the Complaint.

49.

Brookstone denies the allegations made in paragraph 49 of the Complaint.

50.

Brookstone denies the allegations made in paragraph 51 of the Complaint.

Brookstone denies the allegations made in paragraph 51 of the Complaint.

52.

Brookstone denies the allegations made in paragraph 52 of the Complaint.

53.

Brookstone denies the allegations made in paragraph 53 of the Complaint.

54.

Brookstone denies the allegations made in paragraph 54 of the Complaint.

# GENERAL DENIAL

Brookstone denies all allegations contained in the "Wherefore" clause of the Complaint. It also denies all allegations not specifically admitted and denies all allegations contained in all sub-headings or section headings listed in such Complaint. Brookstone denies, furthermore, any and all liability for the acts and omissions alleged in the Complaint.

WHEREFORE, having answered, Brookstone Pharmaceuticals, LLC requests judgment as follows:

- (1) Dismissal of Plaintiff's Complaint, with prejudice;
- (2) Denial all of Plaintiff's requested relief requested, in its entirety;
- (3) Entry of judgment in favor of Defendant and against Plaintiff;
- (4) Tax of all costs and expenses of the instant action to Plaintiff; and
- (5) Such other relief as the Court may deem reasonable and just.

Respectfully submitted July 23, 2008.

# THE WILSON LAW FIRM, P.C.

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# CERTIFICATE OF SERVICE

I hereby certify that on below date, I electronically filed the foregoing "ANSWER" with the Clerk of Court for the United States District Court for the Northern District of Georgia using the CM/ECF system, which will send notification of such filing and electronic copy to:

William B. Hill, Jr., Esq. Ashe, Rafuse & Hill LLP 1355 Peachtree Street, N.E., Suite 500 Atlanta, Georgia 30309-3232

Respectfully submitted July 23, 2009.

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/s/: Simon Jenner
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